



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

HERSHFIELD et al.

Serial No. 09/762,097

Filed: August 23, 2001

For: URATE OXIDASE

Atty. Ref.: 1579-527

Group: 1652

Examiner: Patterson

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

RULE 181 PETITION

The Commissioner is requested to invoke a supervisory authority and have the restriction requirement of November 27, 2001, withdrawn and instruct the Examiner to examine all the pending claims. Consideration of the following in this regard is requested.

A Response to the Office Action of November 27, 2001, has been filed on May 28, 2002.

The Examiner has made the restriction requirement final. See, page 3 of the Office Action dated October 15, 2002 (Paper No. 11).

The present Petition is submitted to be timely filed and consideration of the same prior to the issuance of the Examiner's next substantive action is requested.

The point or points to be reviewed are described below.

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The Commissioner is therefore requested to invoke his supervisory authority and have the restriction requirement of November 27, 2001, withdrawn.

The present application is a 371 of PCT/US99/17678 such that the principles of unity of invention apply to this application, as opposed to restriction. See, MPEP § 1893.03(d) and Example 17 of Annex B of the PCT Administrative Instructions, copies attached. A new Office Action is requested which appropriately follows the principles of unity of invention.

The Examiner asserts in Paper No. 11 that such a further Action will not be issued as the reasoning of the original restriction requirement, which did not apply the principles of unity of invention, would allegedly support the same requirement if the principles of the unity of invention were applied. The applicants respectfully submit that the MPEP clearly explains the substantive difference between restriction practice and unity of invention practice see, for example, MPEP §1893.03(d). In fact, Examiner's are "reminded" of these principles and their separate application in MPEP §1893.03(d), copy attached. The Examiner should not be permitted in the present application to apply the principles of restriction practice where clearly the principles of unity of invention apply.

In fact, the applicants note that the U.S. Patent Office, acting as the International Searching Authority, has found the claims of this application define a single invention. See, attached ISR mailed 2 Feb 2000 in PCT/US99/17678.

The restriction requirement of Paper No. 8 should be withdrawn as being improperly based.

The Commissioner will appreciate that Rule 13.2 PCT (1st sentence) states:

'Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features'.

For the assessment of unity under Rule 13 PCT, it does not matter whether or not certain 'inventions' are obvious or 'distinct' over other 'inventions'. Nor does it matter whether the claimed process steps are materially different or whether the claimed products are materially, structurally or functionally different, as is apparently the basis for the Examiner asserting a lack of unity of invention. See, page 3 of the Office Action dated November 27, 2001 (Paper No. 5) and pages 2-3 of Paper No. 11. Claimed products or processes may differ in any way at all under the principles of unity of invention as long as they possess a relationship which involves a special technical feature.

The only criterion to be assessed in determining unity of invention under Rule 13 PCT is whether groups of claims or 'inventions' have a relationship which involves either the same or a corresponding special technical feature. It is irrelevant whether or not the claimed products or processes differ materially.

Note also that possession of a technical relationship which involves the same or a corresponding special technical feature is not necessarily the same as a specific recital of the same or a corresponding special technical feature.

For the reasons set out below, all the present claims possess unity of invention as defined in Rule 13 PCT.

The present invention relates to a recombinant uricase protein which has been modified to insert one or more lysine residues, and more specifically to a chimeric recombinant uricase protein of two or more mammalian amino acid sequences.

The Examiner has, apparently asserted that each of the protein sequences of SEQ ID NOs:2, 4, 8, 9, 10, and 11; and each of the nucleic acid sequence of SEQ ID NOs:1 and 3 (and corresponding vectors and hosts containing the same); and nucleic acid sequences encoding each amino acid sequence of SEQ ID NOs:8, 9, 10 and 11 (and corresponding vectors and hosts containing the same); and the method of making the claimed DNA are each a separate special technical feature and hence define a separate invention.

Rule 13.2 PCT (2nd sentence) provides a definition of a 'special technical feature':

'The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art'

The feature of claims 1 and 2, for example, which defines a contribution over the art is the chimeric protein of at least two mammalian amino acid sequences sequence which is being modified, which is the sequence of SEQ ID NOs:6 and 7 - resulting in SEQ ID NO:2 (PBC chimera), SEQ ID NO:4 (PKS chimera), SEQ ID NO:8 (PBC amino truncated), SEQ ID NO:9 (PBC carboxy truncated), SEQ ID NO:10 (PKS amino truncated), and SEQ ID NO:11 (PKS carboxy truncated). The relationship between the claims of Groups I-VI and claims 1-5 therefore involves the same special technical feature and there is unity between Groups I-VI.

Group XIII (claims 16 and 17) relates to methods of increasing the PEG attachment sites by altering a uricase protein, as claimed in and exemplified by the proteins of Groups I-VI.

The feature of claims 16 and 17 which defines a contribution over the art is that the protein whose sequence has been altered is the proteins of Groups I-VI. The other features of these claims are known in the art (i.e. mutating a protein) and do not define a contribution over it. The special technical feature of claims 16 and 17 is therefore the proteins of the Examiner's Groups I-VI. The relationship between the claims of Groups I-VI and claims 16 and 17 therefore involves the same special technical feature and there is unity between Groups I-V and Group XIII.

Finally, the special technical feature of claims 6-15, which defines the contribution over the art, is nucleic acids which encode the proteins of the Examiner's Groups I-VI. The relationship between the claims of Groups I-VI and claims 6-15 therefore involves the same special technical feature and there is unity between Groups I-VI and Groups VII-XII.

The restriction requirement should be withdrawn as the previous determination of the U.S. Patent Office, as the International Searching Authority, correctly concluded, as noted above, that the claims of the present application define a single invention. The Commissioner is requested to see the attached copy of Example 17 of Annex B of the PCT Administrative Instructions in this regard.

For completeness, the applicants note that the Examiner appears to have already examined, without any additional undue search burden, more than the elected SEQ ID NO:10 (Group V) as the Examiner has rejected claims 1 and 16-17, but not

claims 2 or 5 which are included in the elected Group, over the cited art. The Examiner's apparent additional search suggests the Examiner has already searched beyond the elected sequence. Reconsideration and withdrawal of the restriction requirement therefore are requested.

The requisite Petition fee is attached for consideration of the present paper. The Commissioner is authorized by the attached cover sheet to charge any missing or deficient fees deemed to be required for consideration of the present Petition to the undersigned's Deposit Account 14-1140.

Grant of the present Petition and withdrawal of the restriction requirement of November 27, 2001, and issuance of an Action on the merits of all the claimed subject matter are requested.

Respectfully submitted,

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By:



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